PEROUSE MEDICAL

K123035

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
**As required by** section 807.92(c)

NOV 2 8 2012

| | |
|---|---|
| Submitter | PEROUSE MEDICAL – 135 route neuve – 69540 Irigny - FRANCE<br>Phone +33(0)4 72 39 74 14<br>Fax +33(0)4 78 51 89 67<br>Website: www.perousemedical.com |
| Contacts | Isabelle JEANTY – Deputy Managing Director, Quality & Regulatory Affairs Director – e-mail : i.jeanty@perousemedical.com |
| Preparation date | August 28 2012 |
| Trade Name | SEAL ONE® Radial Compression Device |
| Common Name | Radial Compression Device |
| Classification Name | clamp, vascular |
| Legally marketed predicate devices | TR BAND ™, 510(k) N° K070423 |
| Description | ***Indications***<br>The SEAL ONE® Radial Compression Device is used for coronary angiography and angioplasty procedures practiced for the radial approach to compress the puncture site.<br><br>***Description***<br>The SEAL ONE® may be used on the right or left wrist. The device placement time should be set on the time indicator, which should subsequently be locked. Wrist strap is secured by a strap which is clipped. The wrist strap can be twisted in to shorten it.<br>Compression is applied by turning the compression knob clockwise.<br>Decompression is done by pressing simultaneously on the safety button and turning the compression knob anticlockwise.<br>It is possible to write on the wrist strap with ballpoint pen or indelible felt pen, to indicate the times at which the device was checked and steps during decompression. The dedicated positions for this are shown by the following symbols at the ends of the wrist strap.<br><br>***Technology***<br>Compression of the radial artery with a compression pad. The compression pad is driven by the compression/decompression knob (inner screwing system).<br>The decompression is made to press the safety button turning the compression knob simultaneously anti-clockwise. |
| Intended Use | The SEAL ONE® Radial Compression Device is used for coronary angiography and angioplasty procedures practiced for the radial approach to compress the puncture site. |
| Performance data | Performance data included with this submission<br>✓ Biocompatibility<br>✓ Safety and functionality – Bench testing<br>SEAL ONE® Radial compression Device has been submitted to testing during design qualification, in accordance with an internal protocol which is enclosed in this submission:<br>– Aspect<br>– Preparation of the system |

**Siège social**
Route du Manoir
60173 Ivry le Temple, France
Tél.: 33 (0)3 44 08 17 00
Fax: 33 (0)3 44 08 17 01

**Division Oncologie & Cardiovasculaire**
Route du Manoir
60173 Ivry le Temple, France
Tél.: 33 (0)3 44 08 17 00
Fax: 33 (0)3 44 08 17 01

**Division Imagerie Interventionnelle & BtoB**
135, Route Neuve
69540 Irigny, France
Tél.: 33 (0)4 72 39 74 14
Fax: 33 (0)4 78 51 89 67

www.perousemedical.com
SAS au capital de 1316702 euros
SIREN 317 883 999 RCS Beauvais
N° TVA intracommunautaire :
FR 01 317 883 999

PEROUSE MEDICAL

| | |
|---|---|
| | – Positioning of the system on the wrist<br>– Compression / decompression of the puncture site<br>– Device positioned and functioning<br>– Removal of the device at the end of process<br>– Used on a patient in the coronary and angiography environment |
| Substantial equivalence | SEAL ONE® Radial Compression Device is substantially equivalent to TR BAND™ |
| Conclusion | Performance data demonstrate safety, effectiveness and substantial equivalence |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Perouse Medical
C/O Isabelle Jeanty
Deputy Managing Director
Quality/Regulatory Affairs Director
135 Route Neuve
69540 Irigny, France

NOV 2 8 2012

Re: 510(k) Number: K123035
Trade/Device Name: SEAL ONE Radial Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 25, 2012
Received: September 28, 2012

Dear Ms. Jeanty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number (if known):** K123035
**Device Name:** SEAL ONE

**Indications for Use:**

The SEAL ONE Radial compression Device is used for coronary angiography and angioplasty procedures practiced in a radial approach to compress the puncture site.

| Prescription Use ✓ | AND/ | Over-The-Counter Use _____ |
| --- | --- | --- |
| (Part 21 CFR 801 Subpart D) | OR | (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123035